IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF OREGON

NI-Q, LLC, Plaintiff, v. **PROLACTA BIOSCIENCE, INC.**, Defendant.	Case No. 3:17-cv-934-SI **OPINION AND ORDER**

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Michael H. Simon, District Judge.

In this action brought by Plaintiff Ni-Q, LLC ("Ni-Q") against Defendant Prolacta Bioscience, Inc. ("Prolacta"), Ni-Q seeks a declaratory judgment of non-infringement and invalidity of U.S. Patent No. 8,628,921 ("the '921 patent"), and contends that Prolacta violated Oregon's Unlawful Trade Practices Act. Ni-Q also asserts an affirmative defense of inequitable conduct, alleging that Prolacta engaged in fraud on the U.S. Patent and Trademark Office

("PTO") in obtaining the '921 patent, among other patents. The Court granted Ni-Q's motion for summary judgment, finding that certain claims of the '921 patent were invalid under 35 U.S.C. § 101 and that even if they were not invalid, Ni-Q did not infringe the patent as a matter of law. Before the Court is Ni-Q's motion for leave to file a second amended complaint to add a new claim alleging a violation of the Sherman Antitrust Act. Also before the Court is Ni-Q's motion for summary judgment, arguing that the claims of the '921 patent are invalid as anticipated under 35 U.S.C. § 102(b) (pre-AIA).

STANDARDS

A. Motion to Amend under Rule 15

Rule 15(a)(2) of the Federal Rule of Civil Procedure provides that the "court should freely give leave [to amend a pleading] when justice so requires." A district court should apply Rule 15's "policy of favoring amendments . . . with extreme liberality." *Price v. Kramer*, 200 F.3d 1237, 1250 (9th Cir. 2000) (quotation marks omitted). The purpose of the rule "is 'to facilitate decision on the merits, rather than on the pleadings or technicalities.'" *Novak v. United States*, 795 F.3d 1012, 1020 (9th Cir. 2015) (quoting *Chudacoff v. Univ. Med. Ctr.*, 649 F.3d 1143, 1152 (9th Cir. 2011)). A district court, however, may, within its discretion, deny a motion to amend "due to undue delay, bad faith or dilatory motive on the part of the movant, repeated failure to cure deficiencies by amendments previously allowed, undue prejudice to the opposing party by virtue of allowance of the amendment, [and] futility of the amendment." *Zucco Partners, LLC v. Digimarc Corp.*, 552 F.3d 981, 1007 (9th Cir. 2009) (alteration in original) (quoting *Leadsinger, Inc. v. BMG Music Publ'g*, 512 F.3d 522, 532 (9th Cir. 2008)). "Not all of the factors merit equal weight. As this circuit and others have held, it is the consideration of prejudice to the opposing party that carries the greatest weight." *Eminence Capital, LLC v. Aspeon, Inc.*, 316 F.3d 1048, 1052 (9th Cir. 2003). Futility of amendment, however, "can, by

itself, justify the denial of a motion for leave to amend." *Bonin v. Calderon*, 59 F.3d 815, 845 (9th Cir. 1995). Generally, however, "[a]bsent prejudice, or a strong showing of any of the remaining [four] factors, there exists a presumption under Rule 15(a) in favor of granting leave to amend." *Eminence Capital*, 316 F.3d at 1052 (alterations added, emphasis in original). When weighing the factors, all inferences should be made in favor of granting the motion to amend. *Griggs v. Pace Am. Grp., Inc.*, 170 F.3d 877, 880 (9th Cir. 1999).

B. Motion for Summary Judgment

A party is entitled to summary judgment if the "movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). The moving party has the burden of establishing the absence of a genuine dispute of material fact. *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986). The court must view the evidence in the light most favorable to the non-movant and draw all reasonable inferences in the non-movant's favor. *Clicks Billiards Inc. v. Sixshooters Inc.*, 251 F.3d 1252, 1257 (9th Cir. 2001). Although "[c]redibility determinations, the weighing of the evidence, and the drawing of legitimate inferences from the facts are jury functions, not those of a judge . . . ruling on a motion for summary judgment," the "mere existence of a scintilla of evidence in support of the plaintiff's position [is] insufficient . . . ." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 252, 255 (1986). "Where the record taken as a whole could not lead a rational trier of fact to find for the non-moving party, there is no genuine issue for trial." *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587 (1986) (citation and quotation marks omitted).

DISCUSSION

A. Motion to Amend

Prolacta argues that Ni-Q's motion to amend should be denied because it is futile, Ni-Q unduly delayed in bringing the motion, and Ni-Q already amended its complaint once before.

The mere fact that Ni-Q previously amended its complaint one time, however, does not support denying the motion. Ni-Q amended its complaint in August 2017, about one year before Ni-Q asserts that it became aware of the facts supporting its allegations of Prolacta's fraud on the PTO. Thus, Ni-Q could not have asserted the proposed antitrust claim when it previously amended its complaint. Ni-Q therefore has not had an opportunity to cure defects and did not in that previous amendment or had the opportunity to bring this new claim and did not in that previous amendment. Accordingly, this factor does not support denying the motion.[1]

Leave to amend may be denied if the proposed amendment is futile or would be subject to immediate dismissal. *Carrico v. City & Cty. of San Francisco*, 656 F.3d 1002, 1008 (9th Cir. 2011). An amendment is futile "only if no set of facts can be proved under the amendment to the pleadings that would constitute a valid and sufficient claim or defense.'" *Barahona v. Union Pac. R.R. Co.*, 881 F.3d 1122, 1134 (9th Cir. 2018) (quoting *Sweaney v. Ada Cty.*, 119 F.3d 1385, 1393 (9th Cir. 1997)); *see also Missouri ex rel. Koster v. Harris*, 847 F.3d 646, 656 (9th Cir. 2017) ("An amendment is futile when 'no set of facts can be proved under the amendment to the pleadings that would constitute a valid and sufficient claim or defense.'" (quoting *Miller v. Rykoff-Sexton, Inc.*, 845 F.2d 209, 214 (9th Cir. 1988))). If the underlying facts or circumstances possibly could "be a proper subject of relief, [a plaintiff] ought to be afforded an opportunity to test his claim on the merits." *Foman v. Davis*, 371 U.S. 178, 182 (1962). The standard for assessing whether a proposed amendment is futile therefore is the same as the standard imposed under Rule 12(b)(6) of the Federal Rules of Civil Procedure, *see, e.g.*, *Miller*, 845 F.2d at 214, although "viewed through the lens of the requirement that courts freely

[1] Ni-Q could have requested leave to amend its complaint in September 2018 when it became aware of the facts supporting its antitrust claim, but this is discussed in the "undue delay" factor below.

give leave to amend when justice so requires." *Barber v. Select Rehab., LLC*, 2019 WL 2028519, *1 (D. Or. May 8, 2019).

Prolacta argues that allowing the amendment is futile because Ni-Q does not assert sufficient facts in its proposed amendment demonstrating that Prolacta has willfully acquired or maintained monopoly power or has injured competition, and that Ni-Q fails to allege a reasonably defined market. In considering futility, the Court does not simply consider the facts alleged, but also considers whether there may be "additional allegations that are 'consistent with the challenged pleading' and that do not contradict the allegations in the original complaint" that would support Ni-Q's new claim. *United States v. Corinthian Colleges*, 655 F.3d 984, 995 (9th Cir. 2011) (quoting *Krainski v. Nev. ex rel. Bd. of Regents of Nev. System of Higher Educ.*, 616 F.3d 963, 972 (9th Cir. 2010)); *see also Quest Integrity USA, LLC v. A.Hak Indus. Servs. US, LLC*, 2016 WL 4533067, at *2 (W.D. Wash. Apr. 8, 2016) ("In determining whether leave to amend should be given, a proposed amendment is futile only if the complaint cannot be saved by further amendment. . . . The Court therefore finds that although the proposed *Walker Process* counterclaims are not particularly well pleaded, they are not futile because they could potentially be saved by further amendment.").

Ni-Q argues that its allegations are sufficient to allege attempted monopolization under 15 U.S.C. § 2 through a *Walker Process* fraud claim.[2] "The traditional claim for attempted monopolization occurs when danger of monopolization is clear and present, but before a full-blown monopolization has necessarily been accomplished." *Alaska Airlines, Inc. v. United Airlines, Inc.*, 948 F.2d 536, 541-42 (9th Cir. 1991). "[T]o demonstrate attempted

[2] The Supreme Court found that enforcement of a fraudulently obtained patent claim could violate the Sherman Act in *Walker Process Equipment, Inc. v. Food Machinery & Chemical Corp.*, 382 U.S. 172 (1965).

monopolization a plaintiff must prove (1) that the defendant has engaged in predatory or anticompetitive conduct with (2) a specific intent to monopolize and (3) a dangerous probability of achieving monopoly power." *Spectrum Sports, Inc. v. McQuillan*, 506 U.S. 447, 456 (1993). For a *Walker Process* monopolization or attempted monopolization claim, a court must "appraise the exclusionary power of the illegal patent claim in terms of the relevant market for the product involved" in order to measure the defendant's "ability to lessen or destroy competition." *Id.* (quoting *Walker Process*, 382 U.S. at 177.

The relevant market as defined by Ni-Q is "the market for breast milk having standardized macronutrient content within the US." The relevant market consists of all products that are "reasonably interchangeable by consumers for the same purposes." *United States v. E. I. du Pont de Nemours & Co.*, 351 U.S. 377, 395 (1956); *Kaplan v. Burroughs Corp.*, 611 F.2d 286, 291 (9th Cir. 1979) ("The principle most fundamental to product market definition is 'cross-elasticity of demand' for certain products or services. Commodities which are 'reasonably interchangeable' for the same or similar uses normally should be included in the same product market for antitrust purposes."). "Reasonable interchangeability" may be determined by looking at price, use, and qualities of the products. *E. I. du Pont*, 351 U.S. at 404. Prolacta argues that Ni-Q's market definition is deficient because regular breast milk that is not standardized with nutrient content or formula is reasonably interchangeable with the nutrient-standardized breast milk. Prolacta, however, previously has submitted expert declarations stating that nutrient-standardized breast milk was necessary in the market, particularly for pre-term babies, and that it is not the same as other products in the market. Prolacta fails to show that the relevant market definition fails as a matter of law. Thus, Prolacta's argument regarding an improper market definition fails to support futility.

Prolacta also argues that Ni-Q fails to show that Prolacta has the requisite monopoly power or danger of obtaining monopoly power because Ni-Q does not allege what market share Prolacta has of the relevant market. Ni-Q alleges that there are only three competitors in the relevant market, and that Ni-Q is a much smaller and newer entrant into the market than is Prolacta. Ni-Q also alleges that the third competitor, Medolac, is also a newer competitor, although Ni-Q does not characterize Medolac as larger or smaller than Prolacta.[3] Ni-Q does, however, allege that Prolacta has long dominated the market, has filed legal actions against Ni-Q and Medolac, has used the legal action against Ni-Q to lessen competition, and that the attempt to eliminate Ni-Q as a competitor has "[given] rise to a dangerous probability that Prolacta would have ended up being the only provider of this type of product in the US." Although these allegations are somewhat conclusory and could benefit from more specific information regarding the estimated market share of Prolacta, Ni-Q, and Medolac, any deficiency could be cured by further amendment and thus does not require denial of the motion to amend for futility.

Prolacta further argues that because Ni-Q has asserted in this litigation that its entry into the market would not cost Prolacta market share, this assertion necessarily means that Prolacta does not and could not have monopoly power. Prolacta argues that if Ni-Q's entrance into the market would not have "cost" Prolacta any market share, then excluding Ni-Q could not have "preserved" any market share for Prolacta. Ni-Q stated that its product is different than Prolacta's fortifier product, is highly unlikely to affect Prolacta's market share, but may well affect Prolacta's ability to charge its current price. Prolacta responded by arguing that it sells other products that do directly compete with Ni-Q's products. Prolacta also later had to lower its

[3] Ni-Q asserts in its brief that Medolac is significantly smaller than Prolacta, but that fact is not alleged in the proposed amended complaint. Ni-Q also asserts in its brief that Prolacta may have up to 90 percent market share. That fact, however, also is not in the proposed amended complaint.

price. The fact that Ni-Q asserted that the sale of its products is highly unlikely to reduce Prolacta's market share of fortifier products does not refute Ni-Q's allegation that Prolacta enforced a fraudulently obtained patent to lessen competition.

Finally, Prolacta argues that Ni-Q fails to allege harm to competition. Prolacta argues that Ni-Q was not precluded from entering the market and has continued to sell in the market throughout the litigation and thus Prolacta's conduct could not have been dangerously close to eliminating competition. Prolacta also argues Ni-Q alleges no affects to competition such as higher market prices, and that the only harm alleged is harm to Ni-Q through attorney's fees, lost revenue, and reputational harm. Prolacta asserts that this is harm to a competitor, and not harm to competition as is required for an antitrust injury.

The Federal Circuit has addressed this issue and explained:

> In this case, however, 3M's unlawful act was in fact aimed at reducing competition and would have done so had the suit been successful. 3M's unlawful act was the bringing of suit based on a patent known to be fraudulently obtained. What made this act unlawful under the antitrust laws was its *attempt* to gain a monopoly based on this fraudulently-obtained patent. TransWeb's attorney fees flow directly from this unlawful aspect of 3M's act. That is, TransWeb's attorney fees "flow[ ] from that which makes [3M's] acts unlawful," *Brunswick* [*Corp. v. Pueblo Bowl-O-Mat, Inc.*], 429 U.S. [477,] 489 [(1977)], and are "attributable to [this] anti-competitive aspect of the practice under scrutiny," *Atl. Richfield* [*Co. v. USA Petroleum Co.*], 495 U.S. [328,] 334 [(1990)]. The "competition-reducing aspect," *id.* at 344, of 3M's behavior was its attempt at achieving a monopoly by bringing the subject lawsuit. 3M's failure to prevail in that lawsuit does not make the resultant attorney fees any less attributable to that behavior, and the attorney fees are precisely "the type of loss that the claimed violations would be likely to cause," *Brunswick*, 429 U.S. at 489. Therefore, TransWeb's attorney fees are both injury-in-fact and antitrust injury.

TransWeb, LLC v. 3M Innovative Props. Co., 812 F.3d 1295, 1309 (Fed. Cir. 2016) (citation omitted) (case citation alterations added, remaining alterations and emphasis in original); *see*

also Quest Integrity, 2016 WL 4533067, at *5 ("In any event, however, the Federal Circuit has recently suggested that attorneys' fees may form the basis for antitrust injury and injury-in-fact on a *Walker Process* claim. That may be enough to sustain Defendant's claim." (citing *TransWeb*)). Ni-Q's allegations of harm are thus sufficient at this stage of the litigation and a failure to allege antitrust injury does not support a finding of futility.

Prolacta has not demonstrated that Ni-Q's proposed Sherman Act claim is futile. Although Prolacta argues that Ni-Q knew about its proposed claim nearly one year ago and could have filed for the amendment sooner, Prolacta does not assert any prejudice was caused by the delay. Undue delay alone is not a basis on which to deny a motion to amend. *See, e.g.*, *In re Tracht Gut, LLC*, 836 F.3d 1146, 1155 n.4 (9th Cir. 2016) ("[W]e note that undue delay alone cannot serve as the basis for the denial of leave to amend."); *Bowles v. Reade*, 198 F.3d 752, 758 (9th Cir. 1999) ("Undue delay by itself, however, is insufficient to justify denying a motion to amend."). Accordingly, because no prejudice to Prolacta was asserted, futility has not been shown, and undue delay alone is insufficient grounds to deny the motion, Ni-Q's motion to amend is granted.

B. Motion for Summary Judgment

Ni-Q moves for summary judgment arguing that the claims of the '921 patent are invalid not only for the reason previously found by the Court, but for the alternative reason that Prolacta violated 35 U.S.C. § 102(b). Section 102(b) creates a statutory bar to patenting in a select group of circumstances, including, as alleged here, if the invention was "in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States." Ni-Q has the burden of showing by "clear and convincing evidence" that there was public use or a sale or offer to sell of a product more than one year before the relevant date, and the product "must satisfy each claim limitation of the patent, though it may do so inherently." *See Elan*

Corp., PLC v. Andrx Pharm., Inc., 366 F.3d 1336, 1340 (Fed. Cir. 2004); *Scaltech, Inc. v. Retec/Tetra, LLC*, 269 F.3d 1321, 1329 (Fed. Cir. 2001).

Ni-Q asserts that Prolacta offered for sale before March 20, 2007 NEO20™, a product that allegedly was produced using the patent's claimed methods. Ni-Q also argues that the hospital's use of NEO20 ™ was public use. "Invalidity under the on-sale bar is a question of law based on underlying questions of fact." *Merck & Cie v. Watson Labs., Inc.*, 822 F.3d 1347, 1350 (Fed. Cir. 2016). "Section102(b)'s on-sale bar is triggered when a claimed invention is: (1) ready for patenting; and (2) the subject of a commercial offer for sale prior to the critical date." *Id.* Similarly, "[t]he public use bar is triggered where, before the critical date, the invention is in public use and ready for patenting." *Polara Eng'g Inc v. Campbell Co.*, 894 F.3d 1339, 1348 (Fed. Cir. 2018) (quotation marks omitted).

Prolacta does not dispute that the product was ready for patenting. Prolacta responds that the product was provided free of charge and thus the distribution was not a commercial offer for sale. Prolacta also argues that the provision of the products was the equivalent of a clinical trial because the products were provided to obtain feedback and the product "sales" were thus experimental. Prolacta further argues that because the patent is a "method" patent providing samples of NEO20™ did not inherently disclose the patent and the Court's previous opinion granting Ni-Q's motion for summary judgment of noninfringement forecloses an argument that NEO20™ was made according to the patent's claimed method. Prolacta also argues that because the recipients of the product were hospitals, it was not a public use.

1. Commercial Offer

In considering whether a purported offer rises to the level of a commercial offer for sale, a court applies traditional contract law principles. *Merck & Cie*, 822 F.3d at 1350. "Only an offer which rises to the level of a commercial offer for sale, one which the other party could make into

a binding contract by simple acceptance (assuming consideration), constitutes an offer for sale under § 102(b)." *Id.* (quoting *Grp. One, Ltd. v. Hallmark Cards, Inc.*, 254 F.3d 1041, 1048 (Fed. Cir. 2001)); *see also Hamilton Beach Brands, Inc. v. Sunbeam Prod., Inc.*, 726 F.3d 1370, 1374-75 (Fed. Cir. 2013) ("An actual sale is not required for the activity to be an invalidating commercial offer for sale. An attempt to sell is sufficient so long as it is sufficiently definite that another party could make a binding contract by simple acceptance. In determining such definiteness, we review the language of the proposal in accordance with the principles of general contract law." (quotation marks and citations omitted)).

To prove an offer for sale occurred before March 20, 2017, Ni-Q submits evidence of email correspondence in February and early March 2007 that demonstrates that Prolacta provided free samples of NEO20™ to at least two hospitals before March 20, 2007.[4] These were provided as part of Prolacta's "Pro-Start" or "Cohort" program. Under this program, Prolacta would provide 60 bottles (about a 30-day supply) of free product to hospitals to feed a specific premature infant who met certain criteria, and offer a discount in pricing for product needed for that baby beyond the initial 30-day supply. Hospitals also could get discounts on future purchases if they entered into an optional contractual arrangement.

It appears evident that Prolacta was willing to enter into contracts for sale of NEO20™ before March 20, 2007. The evidence in the record, however, does not show an "offer" of which the hospital could have entered into a binding contract by "accepting." There is no correspondence in the record discussing price, quantity, delivery, or any such contractual terms.

[4] The email correspondence is with an "Adventist Health Care" facility, and in the body of one email a Prolacta employee notes that the fact "that Johns Hopkins has used our products" likely helped in Prolacta being able to move forward after a presentation was made to the subject facility.

Thus, there remain issues of fact regarding whether Prolacta made an offer for sale before March 20, 2007.

The Federal Circuit has noted that "[e]ven free distribution of a prototype may raise the on-sale bar if it is done to solicit a sale." *Intel Corp. v. U.S. Int'l Trade Comm'n*, 946 F.2d 821, 829 (Fed. Cir. 1991) (citing *Stearns v. Beckman Instruments, Inc.*, 737 F.2d 1565 (Fed. Cir. 1984)). In *Stearns*, however, after the free prototype was sent to the potential purchaser, the record included evidence of a specific price quote for the product and a telephone order that was placed for the product, all before the on-sale bar date. 737 F.2d at 1566.

The concept that distribution of a free product to solicit sales, without more, can trigger the on-sale bar date is inconsistent with the Federal Circuit's later cases emphasizing the requirement that for an offer for sale to trigger the on-sale bar it must be one that would create a binding contract through acceptance. "Acceptance" of free product, absent further communication regarding contract terms, would not create a binding contract. Although it appears from the evidence in the record that Prolacta was attempting to profit from NEO20™ before the on-sale bar date, based on the Court's reading of Federal Circuit precedent, that alone is not enough to trigger the on-sale bar. There is no evidence in the record of an "offer for sale" that qualifies under the standard as articulated by the Federal Circuit.

2. Produced Using the Claimed Method

"Sale of a product . . . produced by performing a claimed process implicates the on-sale bar." *Quest Integrity USA, LLC v. Cokebusters USA Inc.*, 924 F.3d 1220, 1227 (Fed. Cir. 2019); *see also Medicines Co. v. Hospira, Inc.*, 827 F.3d 1363, 1376 (Fed. Cir. 2016) ("It is with vigilance that we have held that the sale of products made using patented methods triggers the on-sale bar, even though title to the claimed method itself did not pass."). Prolacta argues that there is an issue of fact regarding whether NEO20™ was produced using the claimed method

because of the Court's Opinion and Order resolving Ni-Q's motion for summary judgment of non-infringement. In that Opinion and Order, the Court stated: "Genetics Associates' inability to detect unmatched markers below 20 percent contamination renders its test non-infringing." *Ni-Q, LLC v. Prolacta Bioscience, Inc.*, 367 F. Supp. 3d 1221, 1233 (D. Or. 2019). Prolacta's evidence, however, is that its testing facility could determine contaminates at two percent. The Court's finding regarding Genetics Associates' testing that could not determine any contaminants unless they were greater than 20 percent, therefore, does not create an issue of fact relating to Prolacta's testing.

Additionally, Prolacta has submitted declarations from Dr. Martin Lee and Dr. Randolph Nagy stating that all of Prolacta's products were produced using milk from screened donors that was tested to exclude milk from unscreened or unknown donors or commingled milk. These declarations show that Prolacta's products made the "determination" required under the '921 patent. Thus, there is no genuine issue of fact that NEO20 ™ was made using the claimed method.

3. Public Use

"Public use includes any use of [the claimed] invention by a person other than the inventor who is under no limitation, restriction or obligation of secrecy to the inventor." *Netscape Commc'ns Corp. v. Konrad*, 295 F.3d 1315, 1320 (Fed. Cir. 2002) (alteration in original) (quoting *Petrolite Corp. v. Baker Hughes Inc.*, 96 F.3d 1423, 1425 (Fed. Cir. 1996)); *see also Dey, L.P. v. Sunovion Pharm., Inc.*, 715 F.3d 1351, 1355 (Fed. Cir. 2013) (noting that "public use may occur when 'a completed invention is used in public, without restriction.'" (quoting *Allied Colloids Inc. v. Am. Cyanamid Co.*, 64 F.3d 1570, 1574 (Fed. Cir. 1995)). The evidence in the record is that Prolacta provided NEO20™ to the hospital without any restrictions, limitations, or obligations of secrecy. The parents of the infant for whom the product was

supplied signed a consent form, demonstrating that the parents also had knowledge of the product. Prolacta also asked the hospital staff if they would speak with a staff member at a different hospital about the product. This is clear and convincing evidence of use by a person other than the inventor who is under no limitation, restriction, or obligation of secrecy.

"On summary judgment, once [Ni-Q] presented facts sufficient to establish a *prima facie* case of public use, it fell to [Prolacta] to come forward with some evidence raising a genuine issue of material fact to the contrary." *Netscape Commc'ns*, 295 F.3d at 1320-21. Prolacta submitted no evidence that the hospital was subject to some restriction, limitation, or secrecy obligation relating to NEO20™. Prolacta instead argues that because of general doctor-patient privilege and confidentiality requirements, the use cannot be considered public.

The fact that the hospital and its staff could not disclose information regarding a specific patient, however, does not mean the hospital could not disclose information regarding NEO20™. Prolacta provides no evidence that it required the hospital to maintain any confidentiality relating to *Prolacta's product*. Prolacta provides no argument or authority that the milk or formula fed to babies in a hospital is inherently confidential information. Prolacta also does not submit any evidence that it believed that doctor-patient confidentiality applied to the hospital's use of NEO20 ™, thus potentially reducing the need for a separate confidentiality agreement. Indeed, Prolacta's request that Adventist Medical speak to another hospital regarding Adventist Medical's experience with NEO20™ indicates that Prolacta did not believe that information about NEO20™ was subject to doctor-patient confidentiality.

Moreover, "public" use does not require the product use be known by the general public. In the seminal case of *Egbert v. Lippman*, the Supreme Court held: "If an inventor, having made his device, gives or sells it to another, to be used by the donee or vendee, without limitation or

restriction, or injunction of secrecy, and it is so used, such use is public, even though the use and knowledge of the use may be confined to one person." 104 U.S. 333, 336 (1881). The critical considerations are thus the limitations, restrictions, and confidentiality requirements placed by the inventor on the use, even when use is in the medical field. *See, e.g.*, *Barry v. Medtronic, Inc.*, 914 F.3d 1310, 1327 (Fed. Cir. 2019) (analyzing the degree of control (*e.g.*, the limitations and restrictions) over the product and the confidentiality requirements of the tools used to perform surgery); *Pronova Biopharma Norge AS v. Teva Pharm. USA, Inc.*, 549 F. App'x 934, 940 (Fed. Cir. 2013) ("The inquiry is not whether the third person to whom an invention is disclosed makes an open and obvious use of it, but whether the inventor himself has made a use of his invention which is 'public' because it was given to a member of the public without restriction. Given the nature of the inquiry, our case law understandably focuses on the limitations, restrictions, or secrecy obligations associated with a purported public use."). As discussed above, Prolacta provided its product to Adventist Medical without retaining any control over the product and without any requirement of confidentiality.

4. Experimental Use

An inventor may test his invention without triggering the public use bar and thus experimental use negates public use. *Netscape Commc'ns*, 295 F.3d at 1320. In determining whether a particular transaction is commercial or experimental in nature, the relevant inquiry is "whether the primary purpose of the inventor at the time of the sale, as determined from an objective evaluation of the facts surrounding the transaction, was to conduct experimentation." *Allen Eng'g Corp. v. Bartell Indus., Inc.*, 299 F.3d 1336, 1352 (Fed. Cir. 2002); *see also Netscape Commc'ns*, 295 F.3d at 1321 ("To establish that an otherwise public use does not run afoul of section 102(b), it must be shown that the activity was 'substantially for purposes of experiment.'" (quoting *Baker Oil Tools, Inc. v. Geo Vann, Inc.*, 828 F.2d 1558, 1564 (Fed.

Cir. 1987)). The entire transaction must be considered, and a transaction will not be found to be for experimental use simply because the "invention was under development, subject to testing, or otherwise still in its experimental stage at the time of the asserted sale." *Allen Eng'g*, 299 F.3d at 1352.

The Federal Circuit has identified several factors that may be relevant to determining whether a use is experimental:

> (1) the necessity for public testing, (2) the amount of control over the experiment retained by the inventor, (3) the nature of the invention, (4) the length of the test period, (5) whether payment was made, (6) whether there was a secrecy obligation, (7) whether records of the experiment were kept, (8) who conducted the experiment, (9) the degree of commercial exploitation during testing, (10) whether the invention reasonably requires evaluation under actual conditions of use, (11) whether testing was systematically performed, (12) whether the inventor continually monitored the invention during testing, and (13) the nature of contacts made with potential customers.

Polara Eng'g, 894 F.3d at 1348-49.

Considering the evidence in the record and the relevant factors articulated by the Federal Circuit, there is no genuine disputed issue of fact regarding the primary purpose of the free supply by Prolacta of NEO20™ to the hospital. Prolacta states that the products were sent as part of the "Pro-Start" program. Prolacta asserts that the purpose of this program was to "collect real-time data on known patients and to ensure the products' efficacy and usability." The evidence, however, does not support that testing and data collection was the primary or substantial purpose of the provision of product samples.

The "Pro-Start" brochure is a sales brochure that does not ask the recipients of the free product to provide feedback or help with product development. It offers free product so the recipient can appreciate the benefits of the product and obtain discount prices on future purchases. The brochure specifically states that the program is "designed to provide a no-cost

opportunity to try Prolacta products." ECF 159-1 at 3. The brochure also expressly solicits additional, longer-term contracts for sale of the product. Such promotional materials are inconsistent with a claim of experimental use. *See U.S. Envtl. Prod. Inc. v. Westall*, 911 F.2d 713, 718 (Fed. Cir. 1990).

The email correspondence with the Adventist Health Medical facility also did not discuss needing that facility to provide data, help develop the product, or help assess its efficacy or usability. The first email describes the products, attaches information regarding the products, and attaches a summary of benefits of the products. It is a sales pitch email. Another email describes what products were actually shipped and how to use those products. The next email answers a set of questions submitted by a staff member at the hospital. Prolacta provides details regarding dosing, discusses information Prolacta knows because of its testing, and states that it awaits further product order. There is no indication that Prolacta is expecting information from the hospital or that the product supplied is for testing. To the contrary, in answering the hospital's questions, Prolacta cites to its own testing and appears to be a supplier with all the answers and not a supplier looking for data to verify information. None of these emails ask for any data from the hospital or indicate that Prolacta will want data regarding efficacy or usability.

In another email the Prolacta account manager stated she was "curious" how the evaluation on the baby went and whether the hospital had increased the baby's caloric intake, and noted that the hospital should have enough product for a few days but to call to discuss the next order. Although the Prolacta employee expressed curiosity regarding the baby's condition, this curiosity is tied to caloric intake, which is connected to the amount of product that would be needed. The higher the caloric intake, the more product required. This email does not support that Prolacta was providing product for the purpose of gathering data regarding efficacy and

usability. This email also asked the Adventist Medical staff member to communicate with the director at a facility in New York who was considering using Prolacta's products.

Prolacta provides no contemporaneous documentary evidence of any data collected from facilities where free samples were given, correspondence requesting or providing such data, contracts between facilities and Prolacta stating that products would be provided free of charge in return for such data, evidence that Prolacta maintained any records of the purported testing or data collection, or any other similar evidence supporting that the provision of free products was part of product testing or for data collection purposes. The only evidence provided is a declaration from Prolacta's President that states his subjective belief that the "Pro-Start" and "Cohort" programs from 2007 were to test products and that their "goal" was to obtain data. In evaluating a claim of experimental use, however, the Court looks to objective evidence. *Barry*, 914 F.3d at 1330; *see also Netscape Commc'ns*, 295 F.3d at 1321-22 ("Konrad presented no objective evidence to support experimental use. . . . The experimental use negation is unavailable to a patentee when the evidence presented does not establish that he was conducting a *bona fide* experiment. Furthermore, Konrad presented no objective evidence that he maintained any records of testing the remote database object. This failure weighs against him." (citation omitted)). Prolacta provides no objective evidence supporting its contention that Prolacta's provision of free product was to test the product and gather data.

The product of nutritionally standardized breast milk for infants does not appear to be a product that required significant public testing or evaluation under actual conditions of use. The purported test period duration is unknown because when Johns Hopkins used the product is unknown, but based on evidence in the record lasted at least one month immediately preceding the critical date. The assertion of product testing, however, appears more of a justification in

hindsight to avoid the public use bar than actual testing done at the time on the product. Regarding the remaining factors, they do not support that there is an issue of fact regarding experimental use. Prolacta retained no control, required no secrecy obligation, submitted no evidence of actually requesting any testing or data from the product recipient, did not maintain records of testing, clearly commercially exploited the product through the Pro-Start program, did not systematically perform testing during the testing period, did not monitor the invention during testing, and did not have contacts with the potential customers that indicate experimental versus commercial use. The Court thus finds that there is no genuine issue of fact regarding Prolacta's primary or substantial purpose in providing free samples of NEO20™. Prolacta's primary or substantial purpose in distributing the free product was to solicit sales, not for experimentation or product improvement. The distribution of product had a commercial purpose. Thus, Prolacta's argument that there are genuine issues of fact that it was for experimental use is rejected.

5. Conclusion

Ni-Q fails to meet its burden to show that Prolacta made an offer to sell during the relevant time period. Ni-Q has shown by clear and convincing evidence, however, that Prolacta publicly used NEO20™, a product that was produced using the claimed method, more than one year before the relevant application date.

Ni-Q argues that claims 1, 2, 4, 6, 7, 8, and 9 of the '921 patent are invalid based on the public use bar.[5] Prolacta argues that only Claim 1 could be potentially affected. Ni-Q needs to show by clear and convincing evidence that the new limitations in the additional claims are embodied in the NEO20™ that was sent to Adventist Hospital.

[5] Ni-Q originally moved that all claims are invalid under the on sale or public use bar. In its reply brief, however, in response to Prolacta's argument that only Claim 1 could be invalidated by the public use or on sale bar, Ni-Q asserted only that Claims 2, 4, 6, 7, 8, and 9 were also invalid.

Claim 2 adds the limitation that the mammary fluid is human breast milk, and the Court finds through clear and convincing evidence that there is no genuine dispute that NEO20™ was made from human breast milk. Claim 4 adds the limitation that the product contain one or more minerals, including calcium. The Court also finds through clear and convincing evidence that there is no genuine dispute that NEO20™ contains calcium. Claim 6 adds the limitation that STR analysis must be performed, which Ni-Q argues is established through Dr. Lee's declaration. Dr. Lee, however, states that Prolacta's "preferred" analysis was STR. That is not clear and convincing evidence and does not show as a matter of law that the NEO20™ product shipped before the critical date was tested using STR.

Claim 7 adds the limitation that the donated mammary fluid was frozen. Ni-Q cites to Dr. Lee's declaration, in which he generally states that "[t]he claims of the '921 patent, including Claim 1, cover Prolacta's NEO20™ product." ECF 99 at 8. This is insufficient to establish as a matter of law that the donated mammary fluid used to produce the NEO20™ that was provided to Adventist Medical had been frozen.

Claim 8 states that the mammary fluid will be from "a mixture of one or more mammary fluid samples." This is poorly worded. It is unclear how you can have a "mixture" of "one" sample. Additionally, if you just have one mammary fluid sample, which this claim encompasses, then that would be the same as Claim 1. The only portion of this claim that adds to Claim 1 is the "or more" mixture of multiple mammary fluid samples, because Claim 1 includes only one mammary fluid sample. Regardless, because this claim includes a sample of only one, and you can't have a product without at least one mammary fluid sample, the NEO20™ sent to Adventist Medical had to be from at least one mammary fluid sample. Therefore, there is no genuine dispute of fact that the product was covered by this claim.

Claim 9 requires that the biological sample is selected from a group including buccal cells. Ni-Q cites to a document from May 2005 setting out what Prolacta "hopes" to achieve with its DNA testing facility. This document mentions buccal DNA collectors that will be collected as part of the anticipated process. This is not clear and convincing evidence that for the NEO20™ sent to Adventist Medical in 2007, the biological sample was buccal cells.

CONCLUSION

Ni-Q's Motion for Leave to Amend its Complaint (ECF 160) is GRANTED. Ni-Q's Motion for Summary Judgment (ECF 152) is GRANTED IN PART. The Court finds that Claims 1, 2, 4, and 8 of the '921 patent are invalid under 35 U.S.C. § 102(b). The parties are directed to confer on a case management schedule and submit either a joint proposed schedule or separate proposed schedules and contact the Courtroom Deputy within two weeks of this Opinion and Order to schedule a Rule 16 conference.

IT IS SO ORDERED.

DATED this 20th day of September, 2019.

/s/ *Michael H. Simon*
Michael H. Simon
United States District Judge